# Plaintiff's Trial Exhibits with Defendant's Objections

Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. v Barr Laboratories, Inc. Civil Action No. 05cv2308 (PGS)(ES) Judge Peter G. Sheridan Magistrate Judge Esther Salas

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Exhibit Number	Bates Number Begin	Potas Nijerbas Engl	Document Description	Bayer Schering Objection
DX-1	SBPL 00104049	SBPL 00104087	Research Report No. A187	
DX-2	SBPL 00031510	SBPL 00032615	Study Report No. A151	
DX-3	SBPL 00019935	SBPL 00021273	Study Report No. AJ06	
DX-4	SBPL 00017952	SBPL 00018237	Study Report No. 9693	
			W. Krause et al., Determination of	
<u> </u>			Plasma Levels of Spirorenone, a New	
			Aldosterone Antagonist, and One of its	
			Metabolites by High-Performance	
			Liquid Chromatography, Journal of	,
			Chromatography, 1982, Vol. 230, at 37-	
			45.	
DX-5				
			W. Krause et al., Pharmacokinetics of	
İ			the New Aldosterone Antagonist,	
			Spirorenone, in Healthy Volunteers	
			After Single and Repeated Daily	
			Doses, European Journal of Clinical	İ
			Pharmacology, 1983, Vol. 25, at 231-	
			36.	
DX-6				
			Werner Krause and Gerhard Kuhne,	
			Isolation and Identification of	
			Spirorenone Metabolites from the	
			Monkey (Macaca Fascicularis) ,	
			Steroids, 40:81-90 (1982)	
DX-7				
DX-8			U.S. patent No. 6,787,531	
		•	Slide re Progesterone Structure	801, 802 this is a
				demonstrative not
				evidence and is
				inadmissible hearsay;
				does not come from
DX-9				prior art
DX-10	SBPL 02404120	SBPL 02404142	Research Report No. A370	
			Stanczyk, Structure-Function	
}			Relationships, Potency, and	
			Pharmacokinetics of Progestogens,	
DX-11			(1994) at 69-89	

Exhibit				Bayer Schering
Number	Bates Number Begin	Bates Number End	Document Description	Objection
			Slide re Racemic Mixture of	401, 402, 403 this is a demonstrative not
			Norgestrel Enantiomers	
				evidence; does not
DV 10		}		come from prior art
DX-12 DX-13	CDDI 02707065	CDDI 02707102		
DV-13	SBPL 02797065	SBPL 02797193	Research Report No. A166	
			Hartmut Blode, Pharmacokinetics of	
DV 14	CDDY 00500165		Drospirenone, Gynecology Forum	
DX-14	SBPL 02598167	SBPL 02598171	7(1):18-22 (2002)	
	SBPL 00012031	SBPL 00012465	Research Report No. A733	
DX-16	SBPL 02799041	SBPL 02799733	Research Report No. A951	
DX-17	SBPL 02680812	SBPL 02680865	Final Report Version 1.0 No. 308064	
DX-18	SBPL 00010526	SBPL 00010535	Andreas Baumann et al., Use of Rat and Human Liver Slices for the Detection of Steroid Hormone-Induced DNA-Adducts in vitro by Means of the P-Postlabeling Technique, Pharmacology & Toxicology 78:214-223 (1996).  E-mail re Isomerization of	401, 402, 403 article not relevant to any of Defendant's validity defenses; not cited in any of Defendant's expert reports or disclosed in any of Defendant's interrogatory responses
DX-19	SBPL 02615895	SBPL 02615900	drospirenone (ZK 30595) into ZK 35096	
DX-20	SBPL 02323247	SBPL 02323253	Drospirenone (ZK30595) Cytochrome P450 Interaction/Clinical Studies	401, 402, 403 not relevant to any claim or defense in this case
DX-21 DX-22	SBPL 00710845	SBPL 00710854	Letter of Understanding submitted to the FDA from Berlex Laboratories Figures 1-3	
DX-23			Yasmin product label	

Exhibit	Bates Number Begin		Document Description	Bayer Schering Objection
Hamooi	IDAGS ATTITUE DOSTIT	TOZICS MITHAUNTALE	Discurrent Description 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1,	801, 802 hearsay not
				within any exception;
				this document is not
				one of Plaintiffs'
				business records, but
-				was prepared by
				Defendant's expert
DX-24			Yasmin prescription data	
DX-25	SBPL 02677734	SBPL 02677805	Yasmin Business Plan	
	SBPL 02399942	SBPL 02399982	Minutes from the 6th Meeting of	
DX-26			DRSP Team	
DX-27	SBPL 01006163	SBPL 01006322	Schering Annual Report 2003	
				801, 802 hearsay not
				within any exception;
				this document is not
				one of Plaintiffs'
				business records, but
				was prepared by
				Defendant's expert
DX-28			Sales Data	
				801, 802 hearsay not
				within any exception;
		•		this document is not
				one of Plaintiffs'
				business records, but
				was prepared by
			Product Contribution Margin	Defendant's expert
DX-29			Statement	
				801, 802 hearsay not
				within any exception;
				this document is not
				one of Plaintiffs'
				business records, but
				was prepared by
				Defendant's expert
DX-30			Yasmin Detailing Cost 2001 - 2007	

#Exhibit Number	Bates Number Begin	Bates Number End	Document Description:	Bayer Schering Objection
				801, 802 hearsay not
				within any exception;
				this document is not
!				one of Plaintiffs'
				business records, but
				was prepared by
				Defendant's expert
DX-31			Retail Value of Samples	
				801, 802 hearsay not
				within any exception;
				this document is not
				one of Plaintiffs'
		,		business records, but
				was prepared by
				Defendant's expert
DX-32			Direct-to-consumer Advertising	
1				801, 802 hearsay not
				within any exception;
				this document is not
	;			one of Plaintiffs'
				business records, but
				was prepared by
			Yasmin Promotional Expenses 2000 -	Defendant's expert
DX-33			2007	
			Y. Pramar et al., Preformulation	
			Studies of Spironolactone; Effect of	
			pH, Two Buffer Species, Ionic	
			Strength, and Temperature on	
			Stability, Journal of Pharmaceutical	
			Sciences, June 1991, Vol. 80(6), at 551-	
DX-34			53.	
	•		Y. Pramar et al., Quantitation of	
			Spironolactone in the Presence of	
			Canrenone Using High-Performance	
			Liquid Chromatography, Drug	
DV 25			Development and Industrial Pharmacy,	
DX-35			1991, Vol. 17(5), at 747-61.	

r#Exhibit Number	Bates Number Begi	n Bates Number End	Bayer Schering Document Description Objection	
DX-36			Y. Pramar et al., Development of a stable oral liquid dosage form of spironolactone, Journal of Clinical Pharmacology and Therapeutics, 1992, Vol. 17, at 245-48.	
DX-37			Pharmaceutical Society of Great Britain, et al., "Digoxin," The Pharmaceutical Codex: Principles and Practice of Pharmaceutics, Eleventh Ed., The Pharmaceutical Press, London 1979, 283	ļ
DX-38			Ang, et. al., Radionuclide measurement of liquid and solid gastric emptying in normal subjects in Singapore, Ann Acad Med Singapore, 1986 Oct;15(4):511-5.	
DX-39	SBPL 00002490	SBPL 00002496	Research Report No. 4627	
DX-40			International Publication Number WO 97/11680	
DX-41			U.S. Patent No. 5,922,349	
DX-42			Joel T. Hargrove, et al., Absorption of Oral Progesterone Is Influenced by Vehicle and Particle Size, American Journal of Obstetric Gynecology, Vol. 161, No. 4, 948-951, October 1989	
DX-43	GDDY 02500610		U.S. Patent No. 4,002,718	
DX-44 DX-45	SBPL 03500618 SBPL 03500740	SBPL 03500680 SBPL 03500866	Declaration of Lipp  Declaration of Ellman	$\dashv$
DX-46	BARR-DR-025548	BARR-DR-025554	W. Oelkers et al., Effects of a New Oral Contraceptive Containing an Antimineral-corticoid Progestogen, Drospirenone, on the Renin- Aldosterone System, Body Weight, Blood Pressure, Glucose Tolerance, and Lipid Metabolism, Journal of Clinical Endocrinology and Metabolism, June 1995, Vol. 80(6), at 1816-21.	

W. Oelkers et al., Dihydrospirorenone,   A New Progestogen with Antimineral-   corticoid Activity: Effects on   Ovulation, Electrobyte Excretion, and   the Renin-Aldosterone System in   Normal Women, J. Clin. Endo. &     Normal Women, J. Clin. Endo. &     Normal Women, J. Clin. Endo. &     Metab. 1991; 73:837-42     DX-48   M-P 00001242   M-P 00001246   U.S. Patent No. 5,824,667     DX-49   M-P 00000951   M-P 0000955   Declaration of Duesterberg     DX-50   U.S. Patent No. 4,129,564     DX-51   Expert Report on Yasmin by B.     DX-52   SBPL 02322672   SBPL 02322698   Duesterberg and H. Blode     DX-53   M-P 00001996   M-P 00002001   Declaration of Elliesen     DX-54   M-P 00000218   M-P 0000224   Application No. 09/654,227     DX-55   Patent WO 98/04269     Office Action Summary for     Application No. 09/654,227     DX-56   M-P 00000194   M-P 00000201   Application No. 09/654,227     DX-57   U.S. Patent No. 5,534,270     Reply to the 6/4/03 Office Action re     DX-58   M-P 0000218   M-P 0000241   O9/654,227     DX-59   M-P 0000021   M-P 0000215   Declaration of Elliesen     DX-60   M-P 0000043   M-P 0000045   Declaration felliesen     DX-61   M-P 0000043   M-P 0000045   Protocol 96049B     DX-62   M-P 0000047   M-P 0000048   Declaration Study No. 95049     DX-63   SBPL 00407483   SBPL 00407506   Trial Master File 92052     DX-65   SBPL 00076500   SBPL 00076506   Investigation New Drug Application     DX-67   SBPL 00076500   SBPL 00076506   Investigation New Drug Application     DX-68   M-P 00000598   M-P 0000066   Investigation New Drug Application     DX-69   SBPL 00076500   SBPL 000	Exhibit Number	Bates Number Begin	Bates Number End	Document Description	Bayer Schering Öbjection
A New Progestogen with Antimineral-corticoid Activity: Effects on Ovulation, Effects on Ovulation, Effects on Ovulation, Effects on Ovulation, Effects on Newman II. Clin. Endo. & Metab. 1991; 73:837-42				W. Oelkers et al., Dihydrospirorenone.	
DX-47   SBPL 00074890   SBPL 00074895   M-P 00001242   M-P 00001245   DX-48   M-P 00001242   M-P 00001246   U.S. Patent No. 5,824,667	!			• • • • • • • • • • • • • • • • • • •	
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DX-47   SBPL 00074890   SBPL 00074895   Metab. 1991; 73:837-42					
DX-47   SBPL 00074890   SBPL 00074895   Metab. 1991; 73:837-42				the Renin-Aldosterone System in	
DX-48   M-P 00001242   M-P 00001246   U.S. Patent No. 5,824,667		İ		· · · · · · · · · · · · · · · · · · ·	
DX-49   M-P 00000951   M-P 00000955   Declaration of Duesterberg		<u> </u>			
DX-50   U.S. Patent No. 4,129,564					
DX-51		M-P 00000951	M-P 00000955		
Expert Report on Yasmin by B.					
DX-52   SBPL 02322672   SBPL 02322698   Duesterberg and H. Blode	DX-51				
DX-53   M-P 00001996   M-P 00002001   Declaration of Elliesen				1 2 2	
DX-54   M-P 00000218   M-P 00000224   Application No. 09/654,227					
DX-54   M-P 00000218   M-P 00000224   Application No. 09/654,227	DX-53	M-P 00001996	M-P 00002001		
DX-55   Patent WO 98/04269   Office Action Summary for Application No 09/654,227   U.S. Patent No. 5,534,270   Reply to the 6/4/03 Office Action re 09/654,227   U.S. Patent No. 5,534,270   Reply to the 6/4/03 Office Action re 09/654,227   Ox-59   M-P 00000211   M-P 00000215   Declaration of Elliesen   Fred. A. Kincl, et al., Short Communication: Increasing Oral Bioavailability of Progesterone By Formulation, Journal of Steroid Biochemistry, Vol. 9, 83-84, 1978   Ox-60   Biochemistry, Vol. 9, 83-84, 1978   Ox-61   M-P 00000433   M-P 00000475   Protocol 96049B   Letters to participants in Berlex Laboratories Study No. 95049   Ox-63   SBPL 00604014   SBPL 00604015   Memo re Interim Visit   Berlex Laboratories Confidential Investigator's Brochure re Dx-64   M-P 00000489   M-P 00000543   Drospirenone and Ethinyl Estradiol   Dx-65   SBPL 00407483   SBPL 00407506   Trial Master File 92052   Dx-66   M-P 00000598   M-P 00000606   Informed Consent   Investigational New Drug Application				T	
DX-56   M-P 00000194   M-P 00000201   Application No 09/654,227		M-P 00000218	M-P 00000224		
DX-56   M-P 00000194   M-P 00000201   Application No 09/654,227	DX-55				
DX-57   U.S. Patent No. 5,534,270   Reply to the 6/4/03 Office Action re   O9/654,227   O9/654	73.77			· · · · · · · · · · · · · · · · · · ·	
DX-58   M-P 00002386   M-P 00002411   09/654,227   Dx-59   M-P 00000211   M-P 00000215   Declaration of Elliesen		M-P 00000194	M-P 00000201		****
DX-58         M-P 00002386         M-P 00002411         09/654,227           DX-59         M-P 00000211         M-P 00000215         Declaration of Elliesen           Fred. A. Kincl, et al., Short Communication: Increasing Oral Bioavailability of Progesterone By Formulation, Journal of Steroid Biochemistry, Vol. 9, 83-84, 1978           DX-60         M-P 00000473         Protocol 96049B           DX-61         M-P 00000433         M-P 00000475         Protocol 96049B           Letters to participants in Berlex         Laboratories Study No. 95049           DX-62         M-P 00000477         M-P 00000488         Laboratories Study No. 95049           DX-63         SBPL 00604014         SBPL 00604015         Memo re Interim Visit           DX-64         M-P 00000489         M-P 00000543         Drospirenone and Ethinyl Estradiol           DX-65         SBPL 00407483         SBPL 00407506         Trial Master File 92052           DX-66         M-P 00000598         M-P 00000606         Informed Consent           Investigational New Drug Application         Investigational New Drug Application	DX-57	<u> </u>			
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Fred. A. Kincl, et al., Short   Communication: Increasing Oral   Bioavailability of Progesterone By   Formulation   Journal of Steroid   Biochemistry, Vol. 9, 83-84, 1978					
Communication: Increasing Oral   Bioavailability of Progesterone By   Formulation   Journal of Steroid   Biochemistry   Vol. 9, 83-84, 1978	DX-59	M-P 00000211	M-P 00000215		
Bioavailability of Progesterone By Formulation , Journal of Steroid Biochemistry, Vol. 9, 83-84, 1978				i l	
DX-60   Biochemistry, Vol. 9, 83-84, 1978				_	
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Exhibit Number	Bates Number Begi	u Bates Number End	Document Description	Bayer Schering Objection
			M. Aulton, Pharmaceutics: The	
			Science of Dosage Form Design,	
			(1988) Chapter 1, page 6; Chapter 9,	
DX-68			page 136	
DX-69	SBPL 02902458	SBPL 02902468	Research Report No. 4320/H	
DX-70	SBPL 00102254	SBPL 00102267	Yasmin Business Plan	
DX-71	SBPL 02305892	SBPL 02305899	25th Project Team Meeting	
DX-72	SBPL 02314049	SBPL 02314055	27th Project Team Meeting	
				801, 802 hearsay not
				within any exception;
				this document is not
				one of Plaintiffs'
			Client Contact Report re Yasmin	business records
DX-73	SBPL 02593384	SBPL 02593322	Concepts for Market Research	
DX-74	SBPL 02606024	SBPL 02606025	Summary re Reporting Data	
DX-75	SBPL 02588858	SBPL 02588858	Yasmin Marketing Strategies 2002	
DX-76	SBPL 02599496	SBPL 02599497	E-mail re Kaiser - Yasmin	
DX-77	SBPL 02630480	SBPL 02630480	E-mail re Yasmin Best Price	
DX-78	SBPL 02574362	SBPL 02574364	Yasmin Pricing Considerations	
DX-79	SBPL 02602331	SBPL 02602352	Market Research Information	
DX-80	SBPL 01001196	SBPL01001202	Marketing Information	
			Graph re Yasmin Gross and Net Price	
DX-81	SBPL 02771872	SBPL 02771872	per Cycle	
DX-82	SBPL 00950919	SBPL 00950920	E-Mail re Artwork	
DX-83	SBPL 00923241	SBPL 00923243	E-mail re UK Yasmin Study 305043	
DX-84	SBPL 02591237	SBPL 02591238	2003 Yasmin Incentive Plan	
DX-85	SBPL 02594604	SBPL 02594604	E-mail re 2003 Yasmin Target	
DX-86	SBPL 02580793	SBPL 02580796	Yasmin 2003 DTC Budget Recap	
DX-87	SBPL 02601967	SBPL 02601975	E-mail re Yasmin growth rate changes	
DX-88	SBPL 02577429	SBPL 02577430	Contact report	
DX-89	SBPL 02598904	SBPL 02598904	E-mail re Yasmin US Outlook	· · · · · · · · · · · · · · · · · · ·
			Graph re Particle Size Ranges and	
DX-90	SBPL 02655711	SBPL 02655711	Assessment	
DX-91	SBPL 02460624	SBPL 02460630	Declaration of Funke	7
DX-92			German Article	
DX-93		<u> </u>	German Article	
DX-94	SBPL 02419913	SBPL 02419945	Working Report No. MK02E010	
			PCME Technical Exchange Meeting	
DX-95	SBPL 02301750	SBPL 02301758	Drospirenone	

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Number	Bates Number Begin	Bates Number End	Document Description	Objection
			Minutes of the PCME Technical	
			Exchange Meeting on Yasmin 30, DE-	
DX-96	SBPL 02314714	SBPL 02314722	00470	
DX-97	SBPL 00041369	SBPL 00042261	Research Report No. 9970	
DX-98	SBPL 02444743	SBPL 02444750	10th Project Team Meeting	
DX-99	SBPL 02453577	SBPL 02453584	11th Project Team Meeting	
DX-100	SBPL 02444729	SBPL 02444732	Minutes of the DRSP-OC Meeting	
DX-101	SBPL 02453554	SBPL 02453554	14th Project Team Meeting	· · · · · · · · · · · · · · · · · · ·
				Defendant's exhibit
				consists of several
İ				documents, well in
				excess of Research
				Report 6632; Plaintiffs
				object to the inclusion
Ì				of these other
				unrelated document
DX-102	SBPL 00087861	SBPL 00087975	Research Report No. 6632	
DX-103	SBPL 02287828	SBPL 02287859	Research Report No. 6737	
DX-104	SBPL 02797459	SBPL 02797478	Research Report No. 7707	
DX-105	SBPL 00524491	SBPL 00524548	Research Report No. 8235	
DX-106	SBPL 02450241	SBPL 02450250	Research Report No. 8855	***
DX-107	SBPL 02555936	SBPL 02555951	Research Report No. A892	
DX-108	SBPL 02555828	SBPL 02555874	Research Report No. A376	
DX-109	SBPL 02285768	SBPL 02285770	Status Report	
			Statement for Correction of	- · · · · · · · · · · · · · · · · · · ·
DX-110	M-P 00000187	M-P 00000190	Inventorship	
DX-111	M-P 00000182	M-P 00000183	Request for Correction of Inventorship	
			Amendment Related to Inventorship	
	M-P 00002337	M-P 00002359	Issues and Formal Matters	
DX-113	M-P 00000098	M-P 00000102	Notice of Allowability	
	_		Working report, "SH T 470 FA Film-	
			coated Tablets Development of	
			Formulation and Manufacturing	
DX-114	SBPL 02556632	SBPL 02556669	Process"	
DW 115	CDDI 000 (1717		Minutes of the PCME Working Group	
DX-115	SBPL 02264515	· · · · · · · · · · · · · · · · · · ·	Yasmin 30 DE-00470, 22nd meeting	
DW 116	GDDY 0100000		Office Action issued by the Examiner	
DX-116	SBPL 01030254	SBPL 01030259	from the PTO	

Exhibit		Afternoon Afternoon		Bayer Schering
Number  DX-117	Bates Number Begin M-P 00000968	M-P 00000979	Document Description  Development of a New Tablet  Formulation of Theophylline: In Vitro and In Vivo Studies	Objection
DX-118			Arias et al., Dissolution Properties and in vivo Behavior of Triamterene in Solid Dispersions with Polyethylene Glycol, Pharm-Acta-Helv., 1996, Vol. 71(4), at 229-235.	
DX-119	M-P 00000983	M-P 00000987	Shah et al., Preformulation Study Etoposide; Identification of Physicochemical Characteristics Responsible for the Low and Erratic Oral Bioavailability of Etoposide, Pharmaceutical Research, May 1989, Vol. 6, at 408-412.	
DX-120			Berlin et al., Phase I and Pharmacokinetic Study of Micronized Formulation of Carboxyamidotriazole, a Calcium Signal Transduction Inhibitor: Toxicity, Bioavailability and the Effect of Food, Clinical Cancer Research, 2002, Vol. 8(1), at 86-94	
DX-121			Carlson et al., Efficacy and Safety of Reformulated, Micronized Glyburide Tablets in Patients with Non-Insulin Dependent Diabetes Mellitus; a Multicenter, Double-blind, Randomized Trial, Clinical Therapeutics, 1993, Vol. 15(5), at 788- 96	
DX-122			Duclos et al., About a Pharmacokinetic Study of Progesterone in Comelts, Eur. J. Metab. Pharmacokinetic, 1990, Vol. 15(2), Suppl. Abstr. at 226	

Exhibit Number	Bates Number Begin	Bates Number End	Document Description	Bayer Schering Objection
DX-123			Fell et al., Bioavailability of Griseofulvin from a Novel Capsule Formulation, The Journal of Pharmacy and Pharmacology, 1978, Vol. 30(8), at 479-82	
DX-124			Froemming et al., Lyophilized Preparations of Griseofulvins, 2nd Communication, In vivo Release, Abstract of Pharm. Ind., 1986, Vol. 48(7), at 837-40	No objection to actual prior art reference; 801, 802, 901, Plaintiffs object to uncertified English translation attached to German prior art reference.
DX-125			Hartmann et al., Comparison of Galenic Formulations of Orlistat (Tetrahydrolipstatin), A Pharmacological Approach, Abstract of Drug Investigation, 1983, Vol. 5(1), at 44-50	
DX-126			Kohno et al., <i>Pharmacokinetics and Bioavailability of Diltiazem</i> , Abstract of Arzneimittel Forschung, 1977, Vol. 27(7), at 1424-1428	
			PubMed Abstract: GA McClelland et al., The Solubility-modulated Osmotic Pump: In vitro/in vivo release of Diltiazem Hydrochloride , 8(1):88-92	
DX-127			(Jan. 1991)	
DX-128	SBPL 02525183	SBPL 02525226	Clinical Study Proposal No. 307286	
DX-129	SBPL 00266610	SBPL 02828657	E-mail re Updated EURAS data	
DX-130	SBPL 00266619	SBPL 00266620	Cumulative analysis of case reports E-mail regarding Yasmin global case	
DX-131	SBPL 02869171	SBPL 02869171	assessment	
10101		DI D 02007111	E-mail re adverse reactions with	
DX-132	SBPL 02907170	SBPL 02907172	Yasmin	
DX-133	SBPL 00027261	SBPL 00027265	Research Report No. AM90	

r Exhibit Number	Bates Number Begin			Bayer Schering
, namvo	- Pates Millioensegn	a source sentime and the	Document Description	Objection 3
			Shulman LP, Compliance and Contraception: Sharing Responsibility	
DX-134			for Improving Outcomes, The Female Patient, October 1997; 16-20	
DX-135			Peterson et al., Women's Efforts to Prevent Pregnancy: Consistency of Oral Contraceptive Use, Family Planning Perspective 30(1):19-23 (Jan./Feb. 1998).	
			Nikki B. Zite & Lee P.Shulman, New Options in Contraception for Teenagers, Current Opinion in Obstetrics and Gynecology 15:385-389	
DX-136			(2003).	
			Redmond GP et al., Norgestimate and Ethinyl Estradiol in the Treatment of Acne Vulgaris: a Randomized,	
DX-137			Placebo-Controlled Trial, Obstet Gynecol. 1997; 89 (4): 615-22	
				401, 402, 403 the CFR is not evidence, the Court can take judicial notice of
DX-138			21 CFR 312.21	statutes and regulations
DX-139	SBPL 00450717	SBPL 00450717	Volunteer followup results re trial number 92052	
DX-140	SBPL 00091383	SBPL 00091384	Research Report No. 9692	

Exhibit :	Bates Number Begin	Bates Number End		Bayer Schering (-) - Objection
				401, 402, 403
				correspondence
				between counsel is not
				relevant to any claim
				or defense in this case;
	:			remainder of exhibit is
				Study Report 7797,
				which Defendant has
				already identified as a
				trial exhibit and is not
				connected with DX
				141 in any respect
DX-141			E-mail re 30(b)(6) designees	
			Tack lecture re "Studies on pH-	
			Dependent Isomerization of pregnene-	
			17 21-Carbolactones-Are Gastric -	
			Juice-Resistant Dosage Forms	
DX-142	SBPL 03501537	SBPL 03501558	Necessary?"	
			- 1 1 C 4 1 116 4 4 1 116 4 4 1 1 1 1 1 1 1 1 1	
		CDD1 00415010	Testing standard for stability testing of	
	SBPL 02415809	SBPL 02415818	clinical service forms (coated tablets)	
DX-144	SBPL 02293918	SBPL 02293957	Research Study No. 92/127	Exhibit is incomplete,
D. V. 145	GDDI 00017010	CDDY 00017051	Barrensh Barrent No. 4417	missing pages
DX-145	SBPL 00017912	SBPL 00017951	Research Report No. 4417	missing pages
DV 146	CDDI 02461260	CDDY 02451252	Minutes of the Second Meeting of the DHSP Project Team	
DX-146	SBPL 02451350	SBPL 02451353	Diffi Hoject ream	401, 402, 403
				Defendant has
				stipulated to
				infringement, therefore
				Defendant's internal
				documentation
			Amendment to FDA re ANDA 77-527	regarding its generic
			for Drospirenone and Ethinyl estradiol	product are not
			tablets 3.0 mg/0.03 mg 28 Day	relevant
DX-147	BARR-DR-184529	BARR-DR-184532	Regimen	
DV-14/	DAIG-DIC-104323	D/ HCC-D1C-10-332	Trabuttan	

Exhibit Number	Bates Number Begin	Bates Number End	Document Description	Bayer Schering Objection
				401, 402, 403 Defendant has stipulated to infringement, therefore Defendant's internal
DX-148	BARR-DR-184710	BARR-DR-184718	The Weinberg Group Inc. report re Audit of Bioequivalence Studies submitted for 3 mg Drospirenone/0.030 mg Ethinyl Estradiol Tablets (ANDA 77-527)	Tolovani
DX-149	BARR-DR-184637	BARR-DR-184667	Appendix A-Bioanalytical Study Audit Checklists	401, 402, 403 Defendant has stipulated to infringement, therefore Defendant's internal documentation regarding its generic product are not relevant
DX-150	BARR-DR-184668	BARR-DR-184700	Appendix B-Standard Operating Procedures Reviewed for Drospirenone/EthinylEstradiol tablets	401, 402, 403 Defendant has stipulated to infringement, therefore Defendant's internal documentation regarding its generic product are not relevant
DX-151	BARR-DR-184701	BARR-DR-184703	Appendix C-Summary of Batch reject/Reassay Data for Drospirenone Method Validation. Fed and Fasted	401, 402, 403 Defendant has stipulated to infringement, therefore Defendant's internal documentation regarding its generic product are not relevant

*Exhibit	Bates Number Begin	Bates Number End	Document Description	Bayer Schering
				401, 402, 403
				Defendant has
İ		į		stipulated to
				infringement, therefore
				Defendant's internal documentation
				regarding its generic
				product are not
				relevant
DX-152	BARR-DR-033552	BARR-DR-033555	Tab 9 of Barr's ANDA	
DX-153	SBPL 00076331	SBPL 00076334	Letter re IND No. 51,693 Submission	
				401, 402, 403; 801,
				802 Defendant's
	İ			ANDA (iv) notice
			Letter to Berlex Laboratories and	letter is not relevant, also inadmissible
DX-154	BARR-DR-037000	BARR-DR-037013	Schering	hearsay
				<u> </u>
DX-155	SBPL 00710845	SBPL 00710854	Berlex letter to the FDA re IND 51,693	
	SBPL 00101997	SBPL 00102030	Annual report filed with FDA re IND 51,693	
DX-157	SBPL 00263112	SBPL 00263114	Letter to the FDA re NDA 21-098	
DX-158	SBPL 00429221	SBPL 00429266	Research Report A892	
DX-159	SBPL 03501725	SBPL 03501734	Information Disclosure Statement to PTO	
		551 5 053 0175 7		
			Robert Burtner, Structure-Activity	
			Relationships of Some Aldosterone	
			Antagonists, Hormonal Steroids,	
!			Biochemistry, Pharmacology and	
i			Therapeutics: Proceedings of the First	
DX-160			International Congress on Hormonal Steroids , 2:31-41 (1965)	
			J. 1703)	
			G.T. McInnes, Effect of Micronization	
			on the Bioavailability and	
			Pharmacologic Activity of	
			Spironolactone, Journal of Clinical	İ
DX-161			Pharmacology, August-September 1982, Vol. 22(8-9), at 410-17.	
DX-162			U.S. Patent No. 4,904,462	

- Exhibit "Number -	Bates Number Begin	Bates Number End	Document Description	Bayer Schering Objection
DX-163			U.S. Patent No. 6,121,465	
			Basic Information for the Chemical	801, 802
DX-164			Prorenone	inadmissible hearsay
1				801, 802
			Joseph A. DiMasi, Ronald Hansen,	inadmissible hearsay
			Henry G. Grabowski, The Price of	
			Innovation: New Estimates of Drug	
DV 165			Development Costs, 22 Journal Health	
DX-165			Economics 151-185 (2003).	001 000
			Jim Gilbert, Preston Henske and	801, 802
			Ashish Singh, Bain & Co, Rebuilding	inadmissible hearsay
			Big Pharma's Business Model, IN VIVO Vol. 21., No. 10, November	
DX-166			2003.	
DX-167			U.S. Patent No. 4,012,497	
DX-168		,	U.S. Patent No. 4,230,686	
				801, 802
1				inadmissible hearsay;
				this is an article
				authored by one of
				Defendant's experts, it cannot be used to
				prove the truth of what
DV 160				it asserts
DX-169			Overview of the Hatch-Waxman Act	
			·	801, 802 hearsay not within any exception;
				this document is not
				one of Plaintiffs'
				business records, but
	i			was prepared by
				Defendant's expert
DX-170			IMS TRx Data	
				801, 802 hearsay not
				within any exception;
				this document is not
				one of Plaintiffs'
				business records, but was prepared by
				Defendant's expert
DV 171			IMC Description Date	Defendant 3 expert
DX-171			IMS Prescription Data	

Exhibit	Bates Number Begin	Bates Number End	Document Description	Bayer Schering
				801, 802 hearsay not
				within any exception;
				this document is not
				one of Plaintiffs'
ĺ				business records, but
				was prepared by
				Defendant's expert
DX-172			Spreadsheet re Sales 2001 - 2006	
				801, 802 hearsay not
				within any exception;
				this document is not
				one of Plaintiffs'
				business records, but
			Spreadsheet re Berlex Laboratories	was prepared by
			Produce Contribution Margin	Defendant's expert
DX-173			Statement	
=				801, 802 hearsay not
1				within any exception;
1				this document is not
				one of Plaintiffs'
				business records, but
				was prepared by
			Spreadsheet re Yasmin Detailing Costs	Defendant's expert
DX-174			2001 - 2007	
				801, 802 hearsay not
				within any exception;
				this document is not
				one of Plaintiffs'
				business records, but
				was prepared by
			Spreadsheet re Retail Value of	Defendant's expert
DX-175		1	Samples	
	-			801, 802 hearsay not
				within any exception;
				this document is not
				one of Plaintiffs'
				business records, but
] [				was prepared by
			Spreadsheet re Direct-to-Consumer	Defendant's expert
DX-176		1	Advertising	
			110.010000	

Exhibit Number	Bates Number Begin	Bates Number End	Document Description	Bayer Schering Objection 1
				801, 802 hearsay not
ŀ				within any exception;
				this document is not
İ		:		one of Plaintiffs'
				business records, but
				was prepared by
			Spreadsheet re Yasmin promotional	Defendant's expert
DX-177			Expenses 2000 - 2007	
DX-178	SBPL 00267443	SBPL 00267445	FDA Meeting Minutes	
DX-179	SBPL 00205221	SBPL 00205222	FDA Meeting Minutes	
DX-180	SBPL 00263512	SBPL 00263513	FDA Meeting Minutes	
DX-181	SBPL 00263397	SBPL 00263398	FDA Meeting Minutes	
DX-182	SBPL 00076363	SBPL 00076364	FDA Contact Report	
DX-183	SBPL 00076354	SBPL 00076359	FDA Contact Report	
DX-184	SBPL 00076351	SBPL 00076353	FDA Contact Report	
DX-185	SBPL 00076345	SBPL 00076347	FDA Contact Report	
DX-186	SBPL 00076336	SBPL 00076336	FDA Contact Report	
DX-187	SBPL 00076642	SBPL 00076661	FDA Contact Report	
DX-188	SBPL 00076622	SBPL 00076623	FDA Contact Report	
DX-189	SBPL 00076561	SBPL 00076567	FDA Contact Report	
DX-190	SBPL 00076524	SBPL 00076524	FDA Contact Report	
DX-191	SBPL 00264912	SBPL 00264912	FDA Contact Report	
DX-192	SBPL 00264911	SBPL 00264911	FDA Contact Report	
DX-193	SBPL 00685751	SBPL 00685805	Investigator's Brochure	
DX-194	SBPL 00000341	SBPL 00000569	Yasmin NDA Summary	
DX-195	SBPL 00000082	SBPL 00000084	NDA Cover Letter	
	SBPL 00041727	SBPL 00041824	Yasmin NDA: Integrated Summary of	
DX-196			Efficacy	
	SBPL 02775917	SBPL 02775923	K.S. Parsey and A. Pong, An Open-	801, 802 hearsay not
			Label Multicenter Study to Evaluate	within any exception
			Yasmin, and Low-Dose Combination	
	İ		Oral Contraceptive Containing	
			Drospirenone, a New Progestogen,	
			Contraception, 2000;61:105-111	
DX-197				
DX-198	SBPL 00479328	SBPL 00479330	Letter from FDA	
			Robert E. Notari, Biopharmaceutics &	
DV 100			Clinical Pharmacokinetics, 123-124	
DX-199			(3d ed. 1980)	
D3/ 000			Hardy et al., Drug Delivery to the	
DX-200			Gastrointestinal Tract, 83-96 (1989)	

Exhibit Number	Bates Number Begin	Bates Number End	Document Description	Bayer Schering Objection
DX-201	The state of the s		US Pharmacopeia 1790-99 (23 revision 1995)	
DX-202			Clive G. Wilson & Neena Washington, Physiological Pharmaceutics: Biological Barrier to Drug Absorption, 47-70 (1989)	
DX-203			S. S. Davis, I. 0. Hardy, and J. W. Fara, Transit of Pharmaceutical Dosage Forms Through the Small Intestine, Gut, 27, 886-892, 889 (1986).	
DX-204	SBPL 02087480	SBPL 02087627	Working Report LY76	
DX-205	SBPL 02401763	SBPL 02401797	Working Report KE 84	
DX-206	SBPL 02086580	SBPL 02086630	Working Report KQ91E020	
DV 007	SBPL 00099668	SBPL 00099668	FDA Meeting Minutes	Exhibit is incomplete,
DX-207			110 7 5 001 000	missing pages
DX-208			U.S. Patent No. 5,084,277	
DX-209			U.S. Patent No. 5,116,619 Fotherby, K., "Bioavailability of	
DX-210			Orally Administered Sex Steroids Used in Oral Contraception and Hormone Replacement Therapy," Contraception, No. 54, pp.59-69, Elsevier Science, Inc., 1996	
DX-211			Ulrike Fuhrmann, et al., "The Novel Progestin Drospirenone and its Natural Counterpart Progesterone: Biochemical Profile and Antiandrogenic Potential," Contraception, Vol. 54, 243-251, 1996	
DX-212			U.S. Patent No. 4,196,188	
DX-213			Wayne S. Maxson, Joel T. Hargrove, "Bioavailability of Oral Micronized Progesterone," Fertility and Sterility, Vol. 44, No. 5, 822-26, 1985.	
DX-214			U.S. Patent No. 3,146,244	
DX-215			WO 95/17194 (US 5,583,129)	
DX-216			WO 95/26730 (US 5,756,490)	
DX-217			U.S. Patent No. 5,827, 843	

Exhibit Number	Bates Number Bear	Bates Number End	Document Description	Bayer Schering Objection
DX-218		- COXS MINORS DIV	WO 98/27929	Concerns and the concer
DX-219			National Formulary 1799-1951 (18 <sup>th</sup> ed. 1995)	
DX-220	M-P 00002328	M-P 00002328	Interview Summary for 4/6/2004	
DX-221	M-P 00000025	M-P 00000039	Fax re Form 1449 and list of claims	
DX-222	M-P 00000133	M-P 00000149	Fax re Patent Application No. 09/654,227	
DX-223	SBPL 03500665	SBPL 03500669	PubMED for Shah Prior Art Reference	
DX-224	SBPL 03500450 SBPL 03500648	SBPL 03500464 SBPL 03500659	Schering Document from Information Services and Library 7/22/2002	
	SBFL 03300048	SBPL 03300639	Montel et al., Development of a New Tablet Formulation o Theophylline; In vitro and in vivo Studies, Drug Development and Industrial Pharmacy, 1983, Vol. 9(3), at 399-420.	
DX-225				
	SBPL 03501165	SBPL 03501169	Kohno et al., Pharmacokinetics and bioavailability of diltiazem, Abstract of Arzneimittel Forschung, 1977, Vol. 27(7), at 1424-1428.	
DX-226				
			P. Muhn et al., Drospirenone: A Novel Progestogen with Antimineral-corticoid and Antiandrogenic Activity. Contraception. 1995; 51:99-110.	
DX-227				
DX-228			M.J. Rosenberg et al., Compliance, Counseling and Satisfaction with Oral Contraceptives: A Prospective Evaluation, Family Planning Perspectives 1998: 30(2): 89-92 & 104	
DX-229			M.J. Rosenberg and M.S., Waugh, Oral Contraceptive Discontinuation: A prospective Evaluation of Frequency and Reasons. Am J. Obstet. Gynecol. 1998; 179:577-82	

	Bayer Schering					
Exhibit	Bates Number Begin		Document Description	Objection (4)		
			M. Rosenberg et al., Use and Misuse	İ		
}			of Oral Contraceptives: Risk			
			Indicators for Poor Pill Taking and			
			Discontinuation, Contraception 1995;			
DX-230			51:283-88			
DX-230			D. Grimes and K. Schulz, Surrogate			
			end Points in Clinical Research:			
			Hazardous to Your Health . Obstetrics			
1			& Gynecology. May 2005; 105(5):			
DX-231			1114-1118			
211 231			J. Goldzieher and S. Brody,			
			Pharmacokinetics of Ethinyl Estradiol			
		]	and Mestranol, Am. J. Obstet. &			
			Gynecol. 1990; 163(6): 2114-19			
DX-232	_					
			W. Moster and C. Bachrach,			
			Understanding U.S. Fertility:			
			Continuity and Change in the National			
			Survey of Family Growth, 1988-1995,			
			Family Planning Perspectives 1996;			
			28:4-12;			
DX-233			T.O. Dieben et al. Efficacy, Cycle			
1			Control, and User Acceptability of a			
1			Novel Combined Contraceptive			
			Vaginal Ring. Women's Efforts to			
			Prevent Pregnancy: Consistency of			
ļ			Oral Contraceptive Use, Family			
			Planning Perspectives. 1998; 30(1): 19	-		
			23			
DX-234						
DX-235	SBPL 03500853	SBPL 3500853	Study Initiation Visit Report			
DX-236	SBPL 00090500	SBPL 00090627	Study No. 9776			
DX-237	SBPL 00089793	SBPL 00090215	Study No. A470	<del>                                     </del>		
DX-238	SBPL 00088054	SBPL 00089248	Study No. 9274			
DX-239	SBPL 00022666	SBPL 00023055	Study No. AE91			
DX-240		SBPL 00039354	Study No. AG44			
DX-241		SBPL 00029032	Study No. AH37			
DX-242		SBPL 00015088	Study No. AI98			
DX-243		SBPL 00015168	Study No. AI99			
DX-244		SBPL 00030990	Study No. AM91 Study No. AL84			
DX-245	SBPL 00023518	SBPL 00024576	Study No. ALOT			

Exhibit.		Constitution and the second	ar profession	Bayer Schering
Number	Bates Number Begin	Bates Number End	Document Description	Objection * *
DX-246	SBPL 00027259	SBPL 00028060	Study No. AM90	
DX-247	SBPL 00029034	SBPL 00029761	Study No. AM80	
	SBPL 02404120	SBPL 02404120	Study Report A370	Exhibit is incomplete,
DX-248				missing pages
			William E. Evans, Applied	
			Pharmacokinetics: Principles of	
			Therapeutic Drug Monitoring 20-34	
DX-249			(3d ed. 1992)	
			German Patent DE 3022337 (English	
DX-250			version)	
DX-251			U.S. Patent No. 4,927,816	
			Melgardt M. De Villiers, Influence of	
			Cohesive Properties of Micronized	
			Drug Powders on Particle Size	
			Analysis, Journal of Pharmaceutical &	
			Biomedical Analysis, Vol. 13, No. 3,	
			191-198, 1995	
DX-252				
DX-253			U.S. Patent No. 4,826,831	
			U.S. Patent Application No.	
DX-254			08/535,402	
			Edward R. Garrett, Chong Min Won,	
			Prediction of Stability in	
			Pharmaceutical Preparations XVI:	
			Kinetics of Hydrolysis of Canrenone	
			and Lactonization of Canrenoic Acid,	
			Journal of Pharmaceutical Sciences,	
			Vol. 60, No. 12, 1801-09, 1971	
DX-255				
	M-P 00000858	M-P 00000858	Opposition to European Patent, August	
DX-256			19, 2004	missing pages
	BARR-DR-025580	BARR-DR-025589	H. Hess, et al., Mischversuche mit	
			Nieder Dosierten Wirkstoffen und	
			Verschiedenen Exzipientien, Acta	
			Pharmaceutica Technologica, Vol. 21,	
DX-257			No. 4, 245-254, 1994	

Exhibit Number	Bates Number Begin	Bates Number End	Doonment Description	Bayer Schering Objection
DX-258	SBPL 00541285	SBPL 00541292	U. Gaspard, et al., A Randomized Study over 13 Cycles to Assess the Influence of Oral Contraceptives Containing Ethinylestradiol Combined with Drospirenone or Desogestrel on Carbohydrate Metabolism, Contraception, An International Journal, Vol. 67, Number 6, 2003, 423-429	801, 802 hearsay, document is not prior art
DX-259			Physician's Desk Reference, (50th ed. 1996)	
DX-260			Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig, "The Theory and Practice of Industrial Pharmacy," (2d ed. 1976)	
DX-261			Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig, "The Theory and Practice of Industrial Pharmacy," (3d ed. 1986)	
DX-262			"Encyclopedia of Pharmaceutical Technology" (James Swarbrick & James C. Boylan eds., vol. 4, 1991)	
DX-263			J. Haleblian, et. al., Steroid Release from Silicone Elastomer Containing Excess Drug in Suspension, Journal of Pharmaceutical Sciences, Vol. 60, No. 4, 541-45, 1971	_
DX-264			Ang, et. al., Radionuclide Measurement of Liquid and Solid Gastric Emptying in Normal Subjects in Singapore, Ann Acad Med Singapore, 1986 Oct;15(4):511-5.	
DX-265		ļ	Dr. H. Hess et al., Mixing Experiments with Low Dosed Active Ingredients and Various Excipients, Acta Pharmaceutica Technologica, 1975, Vol. 21(4), at 245-54.	

Exhibit Number	Bates Number Begin	Bates Number End	Document Description	Bayer Schering ** Objection **
DX-266	BARR-DR-025590	BARR-DR-025596	N.H. Shah et al., Strategies in the Development of a Tablet Formulation of a Poorly Soluble Drug for Double-Blind Clinical Studies, Pharmaceutical Technology, September 1994, at 152-60.	
			J.C. Shah et al., Preformulation Study of Etoposide: II Increased Solubility and Dissolution Rate by Solid-Solid Dispersions, International Journal of Pharmaceutics, 1995, Vol. 113, at 103-11.	
DX-267				
DX-268			Brazilian Patent Application No. 0014159-3, English Translation, at 553-58.	801, 802, 901 No certification for the English translation
DX-269			Brazilian Patent Application No. 0014159-3, English Translation, at 494-513.	801, 802, 901 No certification for the English translation
DX-270			Brazilian Patent Application No. 0014159-3, English Translation, at 483- 89.	801, 802, 901 No certification for the English translation
DX-271			Brazilian Patent Application No. 0014159-3, English Translation, at 447- 57.	801, 802, 901 No certification for the English translation
DX-272			Brazilian Patent Application No. 0014159-3, English Translation, at 434-40.	801, 802, 901 No certification for the English translation
DX-273	SBPL 02666823 SBPL 02400075	SBPL 02666883 SBPL 02400096	Masterplan (Version Feb. 1997) Minutes of the 5th Meeting of the DRSP Team	
DX-275	SBPL 02413091	SBPL 02413100	Correspondence from Sharon Brown to Dr. Lisa Rarick	
DX-276	SBPL 02400396	SBPL 02400403	Minutes from the 3rd Meeting of	
	SBPL 02421792	SBPL 02421844	DRSP Team Masterplan (Version Aug. 95)	-
	SBPL 02399910	SBPL 02399914	7 <sup>th</sup> Project Team Meeting	
	SBPL 02400206	SBPL 02400209	Memo re Minutes - OC Project Team Meeting & DRSP Meeting with Dr. Heithecker	

Exhibit ■ Number	Bates Number Begin	Bates Number End	Document Description	Bayer Schening Objection
DX-280	SBPL 00450714	SBPL 00450720	Monitoring Interim Visit Report for Trial No. 92052	
DX-281	SBPL 00605103	SBPL 00605104	Agreement between Dr. Ellman/Berlex and study investigator (Dr. Henry)	
DX-282			Guidance for Industry, "Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate- Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System", August 2000, p. 2	801, 802 hearsay, document is not prior art
DX-283			HighBeam Research, "Women lean toward benefits of Yasmin birth-control pill" Chicago Tribune (Chicago, IL), February 21, 2003, Byline: Wendy Navratil http://www.highbeam.com/DocPrint.aspx?DocId=1G1:119480305	
DX-284			HighBeam Research, "Oh, the irony: The Pill sometimes slows libido" Chicago Sun-Times, December 10, 2004, by Lauren Streicher http://www.highbeam.com/DocPrint.as px?DocId=1P2:1558356	
DX-285			HighBeam Research, "Weight-weary women flock to new Pill" Chicago Sun- Times, October 8, 2002, by Anne Marie Chaker http://www.highbeam.com/DocPrint.as px?DocId=1P2:1457623	
DX-286			HighBeam Research, "First Oral Contraceptive With New Class of Progestin, YASMIN(R), Now Available in Pharmacies." PR Newswire, June 21, 2001 http://www.highbeam.com/DocPrint.as px?DocId=1G1:75707729	

Exhibit Number	Bates Number Begin	Bates Number End	Decument Description	Bayer Schering Objection
DX-287			HighBeam Research, "Two Serotonergic Antidepressants, Novel OC Promising for PMS, PMDD." OB GYN News, July 1, 2001, by Kathryn Demott http://www.highbeam.com/DocPrint.as px?DocId=1G1:76877649	
DX-288			HighBeam Research, "Novel OCs May Ease Menses Symptoms. (oral contraceptives)" Clinical Psychiatry News, July 1, 2001, by Kathryn Demott http://www.highbeam.com/DocPrint.as px?DocId=1G1:77875255	
DX-289			HighBeam Research, "Why all the hype about the new Yasmin pill?" (Cosmo Gyno). (mild diuretic may cause some weight losss) (Brief Article) Cosmopolitan, April 1, 2003, by Rachel Grumman http://www.highbeam.com/DocPrint.as px?DocId=1G1:100544412	
DX-290			HighBeam Research, "Birth control/weight-loss pill." (Expert Advice on Health and Fitness). (Yasmin new contraceptive seems to contribute to weight loss) (Brief Article) Ebony, December 1, 2002 http://www.highbeam.com/DocPrint.as px?DocId=1G1:97729811	
DX-291			MedicineNet.com http://www.medicinenet.com/script/ma in/art.asp?articlekey=892&pf=3&page =1	801, 802 hearsay, document is not prior art
DX-292			"Berlex Laboratories Announces FDA approval of YASMIN®, new oral contraceptive with unique progestin', Berlex press release May 14, 2001, reprinted in Science Blog, May 2001, Porter Novelli, http://scienceblog.com/community/old er2001/C200113918.html.	801, 802 hearsay, document is not prior art

Exhibit Number	Bates Number Begin	Bates Number End	Document Description	Bayer Schering Objection
DX-293			http://www.fda.gov/ceder/warn/2003/1 1730.pdf.	401, 402, 403 irrelevant to any claim or defense at issue; prejudicial against Plaintiffs
DX-293	SBPL 01006163	SBPL 01006322	Caboning Annual Donort 2002	2 idilitii
DX-295	SBPL 01007305	SBPL 01000322 SBPL 01007460	Schering Annual Report 2003	
DX-296	SBPL 01007303	SBPL 01007460 SBPL 01006962	Schering Annual Report 2004	
DX-297	SBPL 01000808 SBPL 02447195	SBPL 01006962 SBPL 02447204	Schering Annual Report 2002  19th Project Team Meeting	
DX-298	SBPL 02580785	SBPL 02580788	FDA Letter on Yasmin Promotion	
DX-299	SBPL 02588858	SDI E 02360766	Table for Yasmin Marketing Strategies 2002	
DX-300	SBPL 02590637	SBPL 02590659	Yasmin Pro-Forma: Aggressive Scenario	
DX-301	SBPL 02590709	SBPL 02590716	Yasmin Pro-Forms Tactical Details	
DX-302	SBPL 02602540	SBPL 02602542	Yasmin DTC TV Q&A	
DX-303	SBPL 02630472	SBPL 02630479	Yasmin Net Sales 3 months/6 months Post-Launch	
DX-304	SBPL 02600240	SBPL 02600242	Correspondence between Dr. P. Schewe and Don Atkinson	
DX-305	SBPL 02615974	SBPL 02615978	Southeast Area Business Plan 2005	
DX-306	SBPL 01007741	SBPL 01007751	Schering considerations for investing in American Depositary Receipts	
DX-307	SBPL 02631760	SBPL 02631770	Yasmin Campaign Tracking and Reporting Data (2004)	
DX-308	SBPL 02578678	SBPL 02578691	Yasmin Agency Briefing	
DX-309	SBPL 02672574	SBPL 02672577	FHC West 2001 Yasmin Business Plan	
DX-310	SBPL 02672083	SBPL 02672204	Presentation re DRSP-OC 2004 Business Plan	
DX-311	SBPL 02634252	SBPL 02634257	2003 E07 District Business Plan (Sacramento District)	
DX-312	SBPL 02305854	SBPL 02305863	OHS from Project Team Meeting from J. Frick	
DX-313	SBPL 00075827	SBPL 00075837	24th Project Team Meeting	
DX-314	SBPL 02574362	SBPL 02574364	Yasmin Pricing Considerations	
DX-315	SBPL 02589265	SBPL 02589269	Sample Advertisement	
DX-316	SBPL 02600321		Email re Price Recommendation for Yasmin	
DX-317	SBPL 02601966		Email re Yasmin Average Net Price 2003	
DX-318	SBPL 02631131	SBPL 02631132	Email re Yasmin Pricing	

: Exhibit:		in September 2		Bayer Schering
	Bates Number Begin	Bates Number End	D October 1988	Objection :
	SBPL 02602593		Recommended Price Increase for	
DX-319			Yasmin Fact Sheet	
	SBPL 02611777	SBPL 02611961	Excerpt from EURAS report for Case	
DX-320			Number 1000327010	
DX-321	SBPL 02613821		Email re Yasmin price increase	
	SBPL 02629482		Email re Yasmin price increase	
DX-322			recommendation	
DX-323	SBPL 02629669	SBPL 02629669	Email re Yasmin year end	
DX-324	SBPL 02630480		Email re Yasmin best price	
	SBPL 02633074	SBPL 02633085	Berlex Executive Summary for 1/2003	
DX-325				
	SBPL 02632940	SBPL 02632948	Berlex Executive Summary for	
DX-326			5/17/2002	201 202 1
	SBPL 02631397	SBPL 02631399	NHA Managed Care Focus Spring	801, 802 hearsay not
			2002	within any objection, this document is not
				one of Plaintiffs'
				business records
				business records
DX-327				204 202 1
	SBPL 02570916	SBPL 02570940	Yasmin NHA Update	801, 802 hearsay not
				within any objection, this document is not
				one of Plaintiffs'
1				business records
				business records
DX-328				
	SBPL 02634544	SBPL 02634555	Berlex Executive Summary for 3/2003	
DX-329				
	SBPL 02574341	SBPL 02574343	Key Findings from Yasmin's Advisory	
DX-330			Board Meeting	
DX-331	SBPL 02629033	SBPL 02629036	Email re Kaiser Conference Call	
DX-332	SBPL 02599683	SBPL 02599736	Kaiser net sales	
DX-333	SBPL 02571783	SBPL 02571790	Yasmin Launch Review	
DX-334	SBPL 02577153	SBPL 02577163	Yasmin Forecasting Model	
	SBPL 02577164		Yasmin Forecast Numbers (2001-	-
DX-335			2003)	
DX-336	SBPL 02577189	SBPL 02577202	Yasmin's Managed Care Plans	001 000 1
	SBPL 02577261	SBPL 02577262	NHA Plan for Yasmin	801, 802 hearsay not
				within any objection, this document is not
				one of Plaintiffs'
				business records
				DUSHIESS IECOIUS
DX-337			·	

Exhibit Number	Bates Number Begin	Bates Number End	Document Description	Bayer Schering: 2 12 10 10 10 10 10 10 10 10 10 10 10 10 10
DX-338	SBPL 02577399	SBPL 02577409	Yasmin's Plan Forecast Model	
	SBPL 02588859	SBPL 02588914	Yasmin-"Where are we today?"	
DX-339			Presentation	
D	SBPL 02638856	SBPL 02638858	Berlex Labs January Operations	
DX-340	GDDV 01006554	CDDY 01006406	Commentary	
DX-341	SBPL 01006554	SBPL 01006586	Business Treads: Schering AG Group	
DX-342	SBPL 02570528	SBPL 02570541	Yasmin Creative Storyboard Exploratory Qualitative Research Report	801, 802 hearsay not within any objection, this document is not one of Plaintiffs' business records
DX-343	SBPL 02600460	SBPL 02600463	Storyboard Exploratory Discussion Guide	801, 802 hearsay not within any objection, this document is not one of Plaintiffs' business records
	SBPL 02599165	SBPL 02599169	Consumer Discussion Guide from	801, 802 hearsay not
DX-344			Paragon Research Consulting	within any objection, this document is not one of Plaintiffs' business records
DX-345	SBPL 02578288	SBPL 02578289	Email re Print Ad Concept Testing	
DX-346	SBPL 02631501	SBPL 02631506	Memo re Topline Findings-Yasmin Advertising Concept Research	801, 802 hearsay not within any objection, this document is not one of Plaintiffs' business records
	SBPL 02570705	SBPL 02570719	Yasmin as compared to Ortho-Tri-	
DX-347			Cyclen, Ortho-Tri-Cyclen Lo and Ortho Evra	
DX-348	SBPL 02588942	SBPL 02588952	Yasmin as compared to Ortho-Tri- Cyclen, Ortho-Tri-Cyclen Lo and Ortho Evra	
DX-349	SBPL 02591906	SBPL 02591917	Yasmin as compared to Ortho-Tri- Cyclen Lo and Ortho Evra	
DX-350	SBPL 02592913	SBPL 02592918	Yasmin as compared to Ortho-Tri- Cyclen Lo and Ortho Evra	

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	Bates Number Begin	Bates Number End	2000 miles	Objection
	SBPL 02600640	SBPL 02600652	Sample information for Yasmin (2001)	
DX-351				
	SBPL 02600755	SBPL 02600759	Sample information for Yasmin and	
DX-352			Ortho Evra since Launch	
	SBPL 02602302	SBPL 02602317	Yasmin comparison against other OC	
DX-353			in market	
	SBPL 02602331	SBPL 02602352	Yasmin comparison against Ortho Evra	
DX-354				
DX-355	SBPL 02606024	SBPL 02606025	IMS National Prescription Audit	
DX-356			IMS Master File labeled 185-07 IPS	
	SBPL 01017868	SBPL 01017873	Product Contribution Margin	
DX-357			Statement (1998-mid 2006) 2006-2007 Actual Month and Year to	
	SBPL 01017874	SBPL 01017875	Date Information (Product	
D			Contribution Margin Statements	
DX-358	CDDI 00577200	SBPL 02577409	Yasmin OC Forecast Model	
DX-359	SBPL 02577399	SBPL 02377409 SBPL 00102268	Yasmin Business Plan	
DX-360	SBPL 00102254	SBPL 00102208	2003 Annual Report	
DX-361	SBPL 01006163 SBPL 01010177	SBPL 01000222	SEC Form 20-F/A for Schering	
DX-362	SBPL 01010177	BB1 17 01010219	Aktiengesellschaft	
DA-302	SBPL 01014462	SBPL 01017086	Eidetics Managed Care's Reaction to	801, 802 hearsay not
	BBI E 01014402	BBIBOTOTO	Yasmin	within any objection,
				this document is not
				one of Plaintiffs'
				business records
DX-363				
DX-364	SBPL 02574362	SBPL 02574364	Yasmin Pricing Considerations	
	SBPL 02578280	SBPL 02578281	Email re Yasmin TV Rollout ROI	
DX-365			Projection	
	SBPL 02570916	SBPL 02570924	Yasmin NHA Update Presentation	801, 802 hearsay not
				within any objection,
				this document is not one of Plaintiffs'
				business records
				Judilless 10001ds
DX-366			Pi II Po Constant	
	SBPL 02570944	SBPL 02570945	Memo re Field Force Generated Reminder Items for Yasmin	
DX-367			Reminder items for a simil	

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Number	Bates Number Begin	Bates Number End	Document Description	Objection
	SBPL 02571051	SBPL 02571052	Client Contact Report re PCP Direct	801, 802 hearsay not
			Mail Sample Program	within any objection, this document is not
				one of Plaintiffs'
				business records
DX-368				
	SBPL 02571055	SBPL 02571055	Client Contact Report re Education	801, 802 hearsay not
			Flipchart	within any objection,
				this document is not one of Plaintiffs'
				business records
DX-369				business records
	SBPL 02571063		Client Contact Report re New	801, 802 hearsay not
			Professional Journal Ad for 2003	within any objection,
				this document is not
				one of Plaintiffs' business records
DX-370				dustness records
	SBPL 02577203	SBPL 02577205	Action Items with Timelines and	801, 802 hearsay not
			person(s) Accountable	within any objection,
				this document is not
				one of Plaintiffs' business records
DX-371				ousiness records
	SBPL 02577429	SBPL 02577430	Contact Report with Berlex, RTC and	801, 802 hearsay not
			McCann re 2003 plans for Yasmin to	within any objection,
			leverage ideas	this document is not
			]	one of Plaintiffs' business records
DX-372				ousiness records
	SBPL 02578282	SBPL 02578283	Memo re Yasmin TV Awareness	
DX-373			Tracking	
DV 274	SBPL 02578277	SBPL 02578279	Memo re Yasmin Consumer Print Ad	
DX-374	SBPL 02578288	SBPL 02578289	Testing  Memo re Yasmin Print Ad Concept	
DX-375	SDFL 023/0200	SDFL 023/8289	Testing	
	SBPL 02579421	SBPL 02579422	Letter re Yasmin 2003 DTC Budget	801, 802 hearsay not
			Summary	within any objection,
				this document is not
				one of Plaintiffs' business records
DX-376				ousiness records
	<u> </u>			

Exhibit Number	Bates Number Begin	Bates Number End	Document Description	Bayer Schering Objection 4
DX-377	SBPL 02579450	SBPL 02579732	Contact Report re plan for TV development for Yasmin Heavy-up spending test	801, 802 hearsay not within any objection, this document is not one of Plaintiffs' business records
DX-378	SBPL 02580756	SBPL 02580758	Memo re Yasmin Qualitative Ad Testing	
DX-378 DX-379	SBPL 02580793	SBPL 02580796	Yasmin 2003 DTC Budget Recap	
DX-380	SBPL 02588981	SBPL 02588982	Client Contact Report re concepts for POA3 Materials	
DX-381	SBPL 02589226		Recommended Price Increase for Yasmin Fact Sheet	
DX-382	SBPL 02589979	SBPL 02589980	Contact Report re Yasmin "Right Guy" Ad	
DX-383	SBPL 02591237	SBPL 02591238	2003 Yasmin Incentive Plan	
DX-384	SBPL 02598588	SBPL 02598590	Memo re Updated Minutes/Action items from 3/7/01 Team Meeting	
DX-385	SBPL 02598904	SBPL 02598905	Email re Yasmin US Outlook	
DX-386	SBPL 02594457	SBPL 02594458	Email re Yasmin TV Guide: October	
DX-387	SBPL 02594604		Email re Yasmin Sales target for 2003	
DX-388	SBPL 02594611		Email re Yasmin TV results through November	
DX-389	SBPL 02599165	SBPL 02599169	Paragon Research Consulting Consumer Discussion Guide	801, 802 hearsay not within any objection, this document is not one of Plaintiffs' business records
DX-399	SBPL 02599683	SBPL 02599686	Kaiser net sales 2003-2004	
DV-330	SBPL 02599083 SBPL 02600240	SBPL 026900242	Email re Yasmin Performance and	
DX-391	DDI D 02000240	551 17 02000242	Advertisement	
DX-392	SBPL 02600460	SBPL 02600463	Storyboard Exploratory Discussion Guide	801, 802 hearsay not within any objection, this document is not one of Plaintiffs' business records
DX-392	SBPL 02600755	SBPL 02600759	Sample information of Yasmin and Ortho Evra since Launch	

.Exhibit .				Bayer Schering
Number	Bates Number Begin			Objection
DX-394	SBPL 02601967	SBPL 02601975	Email re Yasmin Growth	
	SBPL 02631131	SBPL 02631132	Email re Followup from Our Meeting	
DX-395	SBPL 02631397	SBPL 02631399	NHA Manage Care Focus	801, 802 hearsay not within any objection, this document is not one of Plaintiffs' business records
DX-396				
DX-397	SBPL 02632940	SBPL 02632948	Berlex Executive Summary for Weeks ending 5/17/2002	
	SBPL 02638856	SBPL 02638858	Berlex Labs January Operations	
DX-398			Commentary	
DX-399	SBPL 02574341	SBPL 02574343	Key Findings From Yasmin Advisory Board Meeting	
	SBPL 02580785	SBPL 02580788	FDA Letter on Yasmin	
DX-400			Promotion/DTC	
DX-401	SBPL 00923241	SBPL 00923243	Email re UK Yasmin study 305043	
DX-402			Albert I. Goldberg, Short Report: Physician Assessments of Patient Compliance With Medical Treatment, Soc. Sci. Med. Vol. 47, No. 11, 1873- 1876, 1998	801, 802 hearsay not within any objection, offered to show truth of the matter asserted
			Hiromu Kondo, et al., Characteristics Of The Gastric pH Profiles Of Unfed And Fed Cynomolgus Monkeys As Pharmaceutical Product Development Subjects, Biopharmaceutics & Drug Disposition, 24:45-51 (2003)	
DX-403	CDDI 02500000	CDDI 02501925	Prosecution History for U.S. Patent	t
DV 404	SBPL 03500000	SBPL 03501835	No. 6,787,531	]
DX-404	<u> </u>		Arrowsmith-Lowe CV	
DX-405 DX-406			Bhaynani CV	
	SBPL 00531336		Blode CV	<u> </u>
DX-407 DX-408	3DFL 00331330		Boghigian CV	
DX-408	<del> </del>		Chambliss CV	
DX-409 DX-410	SBPL 02517080	SBPL 02511781	Duesterberg CV	
DX-410	M-P 00000956	5511,02511101	Duesterberg CV	
DX-411	M-P 00000336		Elliesen CV	
DX-412 DX-413	141-1 00000210		Foster CV	
DVad13	<u>.                                    </u>			

Exhibit Number	Bates Number Begin	Bates Number End	Document Description	Bayer Schering Objection
DX-414	SBPL 02460629	SBPL 02460630	Funke CV	
DX-415	SBPL 00204587		Heithecker CV	
DX-416	SBPL 02306866		Huempel CV	
DX-417	M-P 00002187	M-P 00002195	Lipp CV	
DX-418			McGinity CV	
DX-419			Mossinghoff CV	
DX-420			Nixon CV	
DX-421			Pramar CV	
DX-422	SBPL 00443657	SBPL 00443658	Schellschmidt CV	
DX-423			Schollkopf CV	
DX-424			Shulman CV	
DX-425			Winkel CV	
			Minutes from the 4th Meeting of	
DX-426	SBPL 02412930	SBPL 02412937	DRSP Team	
DX-427	SBPL 02412783	SBPL 02412795	Masterplan	
DX-428	SBPL 02451087	SBPL 02451089	Status Report	
DX-429	SBPL 00024578	SBPL 00027258	Study Report No. 98180	
			Presentation re Oral Immediate	
DX-430	SBPL 02460631	SBPL 02460643	Release Formulation of DRSP	
DX-431	SBPL 02314228	SBPL 02314239	22nd Project Team Meeting Minutes	
DX-432	SBPL 00002072	SBPL 00002083	Research Report No. A982	
DX-433	SBPL 00015429	SBPL 00015444	Research Report No. 7215	
			Contract for the Performace of a	
	SBPL 02521443	SBPL 02521449	Clinical Trial	
	SBPL 02399783	SBPL 02399784	Letter re Berlex Protocol 96049	
DX-436	SBPL 00770347	SBPL 00770347	E-mail re Drug Accountability	
DX-437			Susan Budavari, The Merck Index 3513 (12th Ed. 1996)	
22 131				
			James W. McGinity et al., The Influence of Various Dispersion	
			Methods on the Rate of Dissolution of	
			Sulfabenzamide, Drug Development	
			Communications 1(5), 369-387 (1974-	
DX-438		,,,,,	1975).	
				401, 402, 403 notice
			Barr Laboratories, Inc.'s Notice of	of deposition not
DX-439			Deposition of Dr. Herman Ellman	relevant evidence
			DRSP-GastroPlus Simulation Effects	
			of Particle Size and Dissolution on	
			Predicted Bioavailability, T,C and	
DX-440	SBPL 02461119	SBPL 02461126	AUC	

, Exhibit Number	Bates Number Begin	Bates Number Faul	Document Description	Bayer Schering Objection
		parson moderning	DRSP GastroPlus Simulation Final Assessment of DRSP Particle Size Effect on Bioavailabbility (AUC, c	
DX-441	SBPL 02461083	SBPL 02461092	max)	
			E-mail memo re Meeting on	401, 402, 403 irrelevant, refers to privileged meeting where privileged communications took place
DX-442	SBPL 02461111	SBPL 02461111	DRSP/Formulation	1
DX-443		-	Barr Laboratories, Inc.'s Notice of Deposition of Dr. Wolfgang Heil	401, 402, 403 notice of deposition not relevant evidence
			Plaintiffs Objections and Responses to	401, 402, 403 objections to 30(b)(6) designations are not
DX-444			Defendant's Rule 30(b)(6) Notice	relevant evidence
DX-445			Barr Laboratories, Inc.'s Amended Notice of Deposition of Dr. Heithecker	401, 402, 403 notice of deposition not relevant evidence
DX-446	SBPL 02902458	SBPL 02902468	Research Report No. 4320/H	
DX-447			Barr Laboratories Inc.'s Notice of Deposition of Dr. Lipp	401, 402, 403 notice of deposition not relevant evidence
DX-448			Letter from Eli Lilly and Company re Dr. Lipp's employment	·
DX-449			Barr Laboratories, Inc.'s Notice of Depsition of Jutta Pospisil	401, 402, 403 notice of deposition not relevant evidence
DX-450			Barr Laboratories, Inc.'s Notice of Deposition of Plaintiffs Pursuant to Fed. R. Civ. P. 30(b)(6)	401, 402, 403 notice of deposition not relevant evidence
DX-451	SBPL 02797459	SBPL 02797478	Research Report No. 7797	
DX-452	M-P 00000159	M-P 00000181	Amendment re Inventorship Issues and Formal Matters	
DX-453	SBPL 00094182	SBPL 00099655	IND No. 51,693 File	

# 

				is over 70,000 pages in length. It is needlessly cumulative with numerous other exhibits that Barr has separately designated.
DX-454		II	Schering NDA File	
DX-455 E	BARR-DR-184719		FDA Tentative Approval Letter	
DX-456			U.S. Patent No. 5,583,129	
DX-461			J. C. Chaumeil, Micronization: A method of Improving the Bioavailability of Poorly Soluble Drugs, Meth. and Findings in Experimental and Clinical Pharmacology, Vol 20, no.3 (April 1998)	